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TITLE: An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

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14. ABSTRACT Vasomotor Symptom (Hot Flashes) is a common side-effect of hormone therapy for prostate cancer survivors who experience a rising PSA. In this study, we have developed a paced respiration intervention for men on ADT and we have assessed its feasibility and acceptability. Paced respiration requires patients to use diaphragmatic breathing at a rate of 6 breaths per minute at the onset of a VS episode. Prior studies found that the paced respiration study resulted in a 50% relief of VS among menopausal women. During the first phase of the study, we have conducted and completed 3 focus groups (N=8, N=8, N=6) to aid in the development of the paced breathing intervention (VSI) to control vasomotor symptoms. Focus groups were also used to assess reactions to the initial software design, and user interface. The goal of the software, called "2breathe" and designed for the iPod Touch is to assist patients with the correct breathing rhythm. Usability testing with another group of patients (n = 6) completed the development process. During the second phase of the study, we have conducted a feasibility and acceptability study with patients (N=21) who experience VS. Each participant received an iPod for the duration of the 9-week long study. Participants were instructed in the slow breathing technique and to use the 2breathe application immediately at the first onset of a hot flash episode. Assessments took place at baseline and at 3, 6-, and 9-week follow up. Preliminary data analyses demonstrated that the program and breathing exercise were acceptable to patients and easy to use. Seventy-five percent of patients used the breathing exercise on a regular basis during hot flash episodes. On average, patients used the software 3.5 times a day for an average of 4.6 to 5 hot flashes (at 3wks and 9 weeks respectively). Perceived helpfulness ratings of the intervention to control the number and severity of hot flashes increased over time from 3 weeks to 9 weeks. The preliminary effectiveness indicated by a 35% reduction of hot flash occurrence over the study period. In sum, the slow breathing intervention guided by the 2breathe application proved to be feasible, acceptable and promises to be efficacious to reducing hot flashes among patients on ADT.		
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Project title: An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

Principle Investigator: **Michael A. Diefenbach**

Grant Number: **PC101229**

Introduction

Hormone therapy, or androgen deprivation therapy (ADT), is considered first-line treatment for prostate cancer patients who experience a rising PSA level after definitive treatment (i.e., surgery and radiation). While ADT is effective in slowing the rise in PSA, 70-80% of men receiving this treatment experience vasomotor symptoms (VS), also known as hot flashes.¹ These symptoms often negatively impact patients' mental health, sleep, resulting in increased fatigue and diminished quality of life.² Although there are pharmacological treatments available to manage hot flashes, many patients choose not to take them because of potential interference with cancer control and an increased risk of additional side effects.³⁻⁵ Thus, there is a strong need, supported by our formative research with patients on ADT, for a non-pharmacological approach to manage hot flash symptoms. The aims of this study were to develop and to establish the feasibility and acceptability of a behavioral intervention to reduce hot flashes among patients who are following an ADT regimen for their rising PSA. Specifically, we aim to (1) develop a breathing exercise application for the iPod touch platform; and (2) assess the feasibility and acceptability of this intervention among advanced prostate cancer survivors on hormone therapy. To reach these goals, we have developed an application, titled "2Breathe," for Apple's iPod Touch platform to help men apply the breathing techniques and we are currently evaluating its feasibility and acceptability.

Keywords

Androgen deprivation therapy (ADT)
Vasomotor symptoms (VS) or "hot flashes"
Non-pharmacological approach
iPod Touch application platform
"2Breathe" and "2Play"

Accomplishments

Our study team, led by Michael A. Diefenbach, PhD, has made considerable progress in the third year of the project entitled "An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy." We have now successfully recruited, enrolled, and followed up with n=21 participants from both the Icahn School of Medicine at Mount Sinai and the James J. Peters VA Medical Center. Further detail about our progress during the last 3 years is described below.

Year 1:

Task 1: Institutional Review Board Process

Protocol and all required documents have been submitted to the Institutional Review Boards (IRB) of Mount Sinai School of Medicine's (MSSM) and the James. P. Peters VA Medical Center (JJP VAMC). After MSSM and James P. Peter VA Medical Center approved the protocols, all approved study materials were submitted to the Department of Defense's Institutional Review Board (IRB). Study personnel updated their required HIPPA and IRB training. In addition to the CITI training at MSSM, all personnel have obtained the following 1) HIPPA authorization, and 2) Privacy and Data Security of MSSM and JJP VAMC. All recruitment personnel have been trained to explain and to obtain informed consent from study participants.

Task 2: Phase I of the software development

In June of 2011, the Principle Investigator met with co-investigators (Dr. Nihal E. Mohamed, Dr. Simon Hall, and Dr. Tracey A. Revenson) and consultants (Kevin Durr, and Dr. William Dudley) to discuss contents of the iPod training, intervention and assessment modules. Based on this meeting we developed the script content and assessments for the vasomotor symptoms paced respiration training, intervention, and assessment modules. During subsequent meetings wire frames (i.e., prototypical mock-ups of the iPod software interface), which contain elements such as animation, music samples, voiceover, and selected actors were discussed. A contractor composed a short piece of music to support the appropriate breathing rhythm. Short video clips were selected to illustrate the breathing pattern visually. Additional features of the software are its ability to track the frequency and duration of hot flashes and to let participants rate the severity of the hot flash they just experienced. A summary screen visualizes all recorded hot flashes within a given week.

Task 3: Refine and finalize Focus Group Guides

Next, the team revised, expanded and finalized the focus group guide and its procedures. The revised guide was submitted and approved by all relevant IRBs. Results of the focus groups have informed the Vasomotor Symptom Intervention (VSI) adoption and its development process.

Task 4: First set of 2 focus groups: preparation, conduct, and analyses

Of the planned focus groups, the first two groups (n = 16; 8 men each per group) would mainly focus on the nature of vasomotor symptoms (VS), severity, frequency and their impact on their daily lives. These first two focus groups also gauged the men's reaction to the breathing intervention techniques. Focus groups were conducted at the JJP VAMC. Men were African American, on average 65years old, and have been on ADT an average of 6 months. All suffered from hot flashes of various severities, ranging from mild to severe. The hot flashes were described by patients as being accompanied by profuse sweating, nausea, shivering, head warmth, and dizziness, among other symptoms. There was no consensus on what time of day the hot flashes occur, what may trigger them, and how long they last. While one patient experienced them every day at 5 AM, others say they happen all the time, and yet others claim that it changes every day and there are no specific triggers. Some patients experienced their hot flashes for no

more than five minutes while others say they lasted between 10 and 15 minutes. All patients were excited about the potential of a non-pharmacological intervention for VS control.

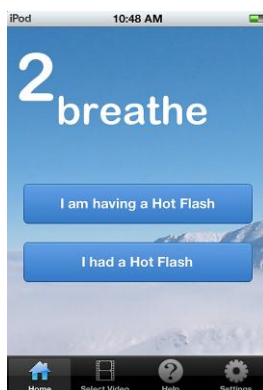
Task 5: Phase II of the software development

The information from the first two groups was useful in developing the first prototype of the application. Because the duration of the hot flash varied within and between-subjects, this information will be recorded by the application and used for further analysis. When the patient is experiencing a hot flash and starts the paced respiration exercise with the help of the software the application will record how long the hot flash lasted and at what time it occurred. The software will also prompt the user to record the severity of the hot flash (i.e., how “bad” it was.) This information will then be summarized on a chart for the patient’s reference, allowing him to follow trends.

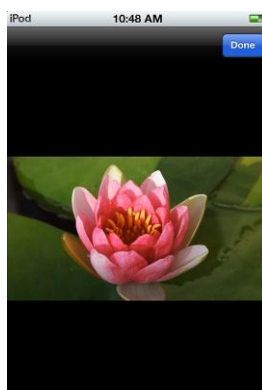
Participants in the first two focus groups were also probed about the feasibility of using a breathing exercise application. We realized that men might not always use the software to control their hot flashes and thus we incorporated an additional feature into the application that allows users to record VS information once the hot flash is over. After the patient has experienced a hot flash, he can open the application and select “I Had a Hot Flash,” and enter the pertinent information into the application (i.e., time, intensity, and duration of the hot flash.)

Task 6: Second set of 2 focus groups: preparation, conduct, and analyses

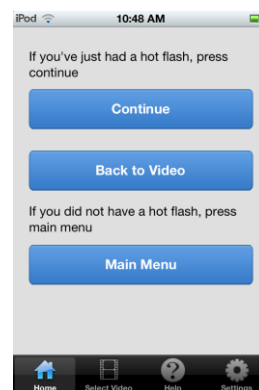
The third focus group (n = 6) focused on contents and potential usability of the iPod-based VSI. Again, men were African American, recruited from JJP VAMC, who suffered from hot flashes. We showed a comprehensive layout of the program, including all relevant screens, graphics, videos, and music clips. Participants at first examined the wireframes without further detailed explanation. Men were asked whether they could intuit the functions of different areas of the screen and queried how they would interact with the program. All patients grasped the design and layout without problems. They stated preferences for certain graphics, videos, and music clips. Suggestions were also given for the “distraction” control group in which the participants will be given several options of games to play rather than the breathing exercise. All completed focus groups were transcribed for analysis and results were incorporated into the final version of the software.



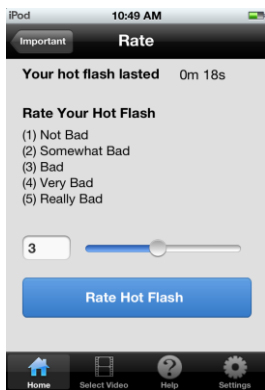
Home screen



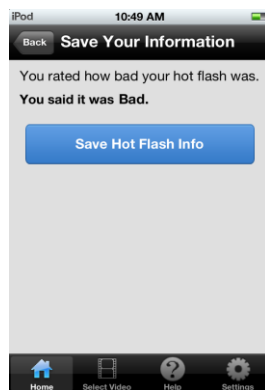
In this video the flower is opening and closing at the exact 10 sec rhythm (5 sec inhale; 5 sec exhale). A voice further intonates inhale/exhale and the music’s beat follows the same rhythm



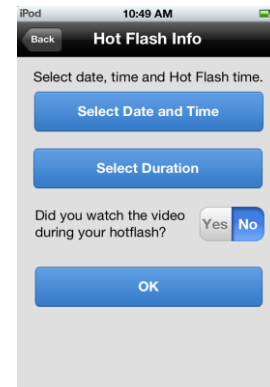
Continuation Screen



Rate Severity of Hot Flash



Save Hot Flash Information



Date, Time, Duration screen to be used to enter hot flash information if program was not used during the breathing exercise

Year 2:

Task 7: Conduct Beta Test and Revision of VSI

During July 2012 to September 2012, Kevin Durr and his development team finalized the iPod application. Twelve iPod Touches were purchased in July 2012 and were prepared for software installation (i.e., extraneous software was stripped and the home screen was changed). In October of 2012 we conducted usability testing with the software which was installed on two iPod Touches for testing purposes. Participants in the usability testing were again men on ADT who experienced hot flashes (N=6). During this session, the PI demonstrated the use of the iPod, the two software programs, 2Breathe (intervention) and 2Play (attention-control), along with the breathing exercise. Participants then had a chance to try out the software. Despite limited or no experience with an iPod and Apple's operating system, participants, after a brief introduction, had no difficulties operating the device, calling up the software, and entering the necessary data. Overall, participants displayed great interest in the software and reviewed it very positively.

Overall, the development process was a great success and can serve as a model of how to involve stake holders. Patients were part of the development process from the very beginning. They provided crucial information about the clinical problem, detailing the magnitude and frequency of vasomotor symptoms. They informed us about the impact of these symptoms on their sleep, fatigue, daily activities and overall quality of life. Patients surprised us with their willingness to embrace non-pharmacological methods to control their symptoms. Patients were also supportive of our software development efforts, giving us valuable feedback on the "look and feel" of the wireframes of the software, including their preferred music choices. Finally, patients were willing participants in the usability testing, spending time exploring all aspects of the software and critiquing and commenting on the functioning application. Because patients were involved from the very beginning through all aspects of development, there was no need for further changes to the beta version.

Task 8: Participant recruitment and baseline and follow-up data collection of the feasibility study

As per Task 8 of the Statement of Work, as of August 2013, we began recruitment of patients into the feasibility study and collected baseline and follow-up data on all enrolled study participants. Participants were recruited from the Icahn School of Medicine at Mount Sinai and the James J. Peters VA Medical Center. Participants were assessed at baseline and at follow-up assessments (at 3-, 6-, and 9-weeks). A database was created for all participant-generated data, consisting of their usage of the 2Breathe and 2Play applications and the responses to the questionnaires.

Year 3:

Continuation of Task 8: Participant recruitment and baseline and follow-up data collection of the feasibility study. We filed a one year no cost extension in July 2013, and received approval for the extension in October, 2013. We hoped to recruit n=66 prostate cancer patients experiencing hot flashes as a result of hormone therapy into our feasibility and acceptability study. Despite a promising start of accruing 10 patients at the start of the feasibility study, since September 2013 we experienced significant delays in patient recruitment. The delays were caused by a change in leadership at the department of Urology. Our then chairman and collaborating investigator Dr. Simon Hall unexpectedly vacated the position as chairman and a new physician, Dr. Ash Tewari, was hired to replace him. During the ensuing transition period all clinical studies came essentially to a standstill as Dr. Tewari needed to be included in the study protocol, moved into his new offices and started to increase his patient volume. To partially counter these delays we included two additional physicians – Dr. Seth Blacksbury, MD at the Icahn School of Medicine at Mount Sinai and Dr. George Dawson, MD, at the James J. Peters VA Medical Center. Both physicians are radiation oncologists. In February 2014, Dr. Blacksbury left the Icahn School of Medicine, and referred us to another physician, Dr. Gupta, whose patients might potentially fit our inclusion criteria. The paperwork was filed to our IRB office to add him into the study.

Task 9: Interim Analyses

We have presented preliminary data at two national conferences. In April 2014, we have presented our primary data as a poster presentation at the Society of Behavioral Medicine in Philadelphia. The poster session generated a lot of interests. We were also selected to present our software at a showcase event for innovative software. This latter event led to further collaborations to use the program with pain patients (collaborator Dr. Francis Keefe, Duke University) and with breast cancer patients (Dr. Kerry Sherman, McQuarie University, Queensland, Australia).

Michael A. Diefenbach, PhD; Simon J. Hall, MD; Phapichaya Chaoprang Herrera, MA; Jessica Lake, BS; Matt A. Hall, MA; Vinay Patel, BS; Glen W. McWilliams, MD; George A. Dawson, MD. **An iPod Intervention to Control Hot Flashes in Advanced Prostate Cancer Patients on Hormone Therapy.** Poster presented at the Society of Behavioral Medicine, Philadelphia, PA, April 2014.

The second presentation was at the NCI and ACS sponsored survivorship conference in Atlanta:

Michael A. Diefenbach, PhD; Simon J. Hall, MD; Phapichaya Chaoprang Herrera, MA; George A. Dawson, MD; Glen W. McWilliams, MD; Vinay Patel, BS; Jessica Lake, BS; Matt A. Hall, MA. **An iPod Intervention to Control Hot Flashes in Advanced Prostate Cancer Patients on Hormone Therapy.** Poster presented at the 7th Biennial Cancer Survivorship Research Conference, Atlanta, GA, June 2014.

In this study we have established the feasibility and acceptability of a paced respiration exercise among prostate cancer patients who receive ADT. Our interim analysis on the usage of the program shows that the program and breathing exercise were easy to use. 75% of the patients reported using the program on a regular basis. On average, patients used the software 3.5 times a

day for 4.6 to 5 hot flashes (at 3 weeks and 9 weeks respectively). Perceived helpfulness ratings of the intervention to control the number and severity of hot flashes increased over time from 3 weeks to 9 weeks. Patients reported a 35% decline in hot flash occurrence over the study period, thus establishing preliminary effectiveness.

Task 10: Final Analyses and Report Writing

As of September 2014, we have enrolled and successfully followed n=21 patients from both sites. We are currently moving towards completing our final analyses and preparing manuscripts for publication.

Appendices

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An iPod Intervention to Control Hot Flashes in Advanced Prostate Cancer Patients on Hormone Therapy



Michael A. Diefenbach, Ph.D.; Simon J. Hall, MD, Phapichaya Chaoprang Herrera, MA; Jessica R. Lake, BS; Matt A. Hall, MA; Vinay Patel, BS; Glen W. McWilliams, MD¹; George A. Dawson, MD¹

Department of Urology, Icahn School of Medicine at Mount Sinai; New York, NY; ¹James J. Peters, VA Med Ctr, Bronx, NY

Introduction

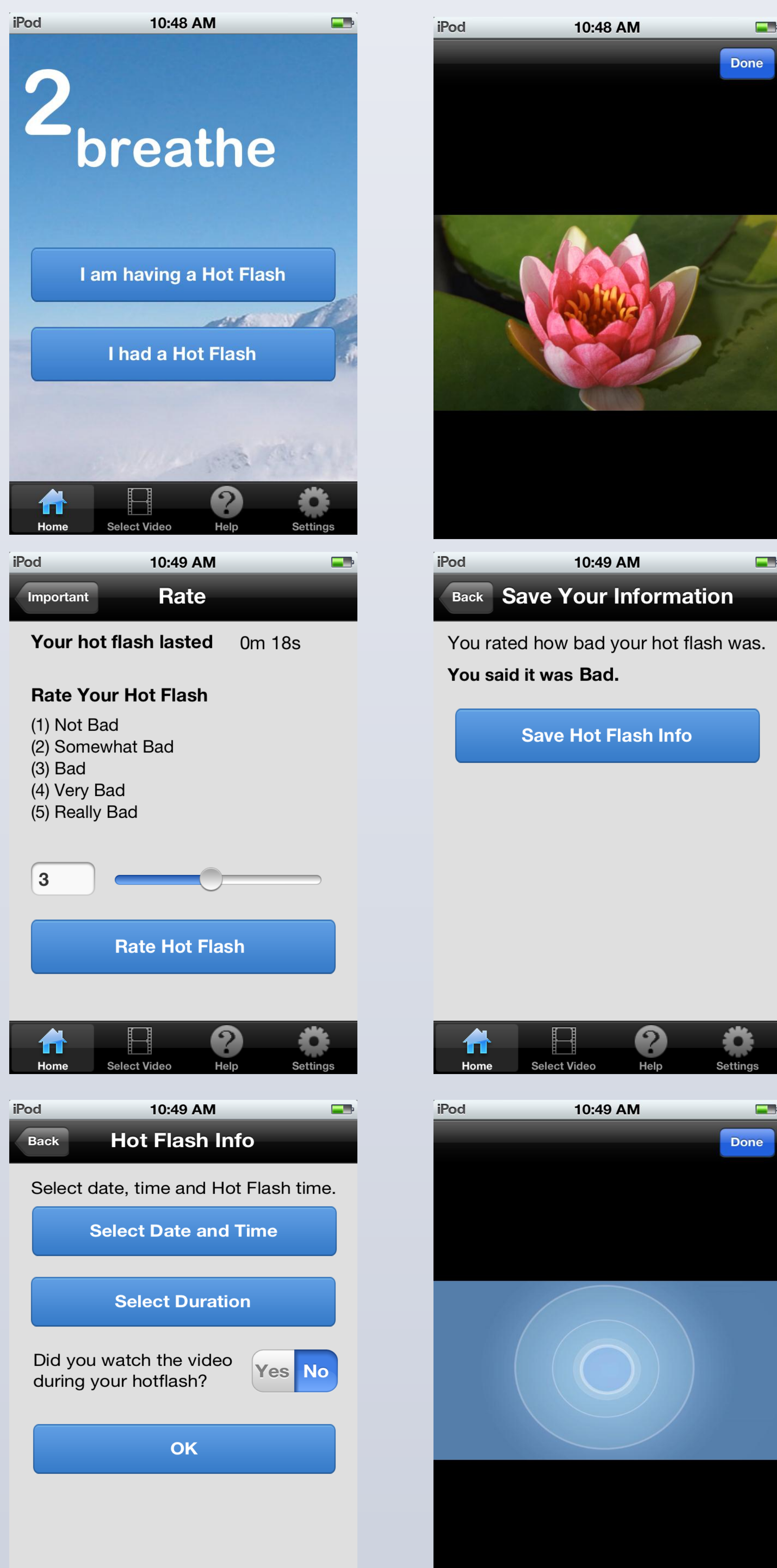
Androgen deprivation therapy (ADT) is considered first-line treatment for prostate cancer (PC) survivors after experiencing a rising prostate specific antigen (PSA). Although effective in slowing the rise in PSA, ADT has side effects, such as vasomotor symptoms (VS; also known as hot flashes), total loss of libido, and loss of muscle mass. Up to 50% of men report VS severe enough to require treatment. Elevated levels of VS are associated with sleep and mood disturbances and overall reductions of QOL

Current available pharmacological approaches for symptom control are associated with additional side effects and might interfere with cancer control. At this stage of their illness trajectory, men are often reluctant to take additional medications. Thus a non-pharmacological approach is needed.

The purpose of this study is to determine the feasibility, acceptability, and preliminary efficacy of such a non-pharmacologic approach to VS control: A newly developed paced-respiration breathing technique, guided by an iPod Touch® application to manage hot flashes.

Paced Respiration Intervention

We adopted a paced respiration technique for prostate cancer patients on ADT that was successful in controlling vasomotor symptoms among menopausal women. To aid men in slowing their breathing to the recommended frequency of 6 breaths/min, we developed an iPod based software program with appropriate graphic animations and music. The software will also collect data in real time about occurrence, duration, and severity of the hot flash.



Study Design

N = 17 prostate cancer patients have been enrolled in the study so far. Each participant receives an iPod for the duration of the 9-week long study. Participants are instructed in the slow breathing technique and to use the ²Breathe application immediately at the first onset of a hot flash. Assessments take place at baseline and at 3, 6-, and 9-week follow up. ²Breathe usage data has been extracted from each iPod

Results

Table 1: Demographics

Variable	N = 17	Mean (SD) or %
Age	17	67 (9.96)
Ethnicity		
African American	14	82%
Caucasian, Hispanic, other	3	18%
Education		
High School	11	65%
College	6	35%
Marital Status		
Separated/Divorced/Single	10	60%
Married	7	40%

Table 2: Acceptability

Variable	%
How easy was the program to use ?	Quite a bit - 42%; Extremely - 58%
How easy was the breathing exercise?	Moderately - 8%; Quite a bit - 17%; Extremely - 75%
How often did you use the program when experiencing a hot flash?	Rarely - 8%; Sometimes - 17%; Most of the time - 67%; Always - 8%.

Table 3: Preliminary Effectiveness

Variable	Baseline M (SD)	3 Weeks M(SD)	9 Weeks M(SD)
How many HF/day?	7.7 (6.6)	4.58 (2.64)	5 (4.33)
How often used exerc per day?		3.58 (2.50)	3.5 (3.34)
Helpful reducing number of hot flashes?		Not at all – 25% Little bit – 17% Moderately –33% Quite a bit - 25% Extremely - 0%	Not at all – 9% Little bit – 9% Moderately –36% Quite a bit - 9% Extremely - 27%
Helpful reducing severity of hot flashes		Not at all – 25% Little bit – 0% Moderately –25% Quite a bit - 33% Extremely - 17%	Not at all – 9% Little bit – 9% Moderately –9% Quite a bit - 27% Extremely - 36%

Conclusions

- In this pilot study we have established the feasibility and acceptability of a paced respiration exercise among prostate cancer patients who receive ADT.
- Program and breathing exercise were easy to use
- Program was used by 75% of patients on a regular basis
- Patients used software on average 3.5 times a day for 4.6 to 5 hot flashes (at 3wks and 9 wks respectively)
- Perceived helpfulness ratings of the intervention to control the number and severity of hot flashes increased over time from 3 wks to 9 wks
- Preliminary effectiveness indicated by a 35% reduction of hot flash occurrence over the study period.

Acknowledgement

This project was supported by Grant PC101229 from the Department of Defense of the US Army Medical Research and Materiel Command to M.A. Diefenbach, Ph.D.

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Introduction

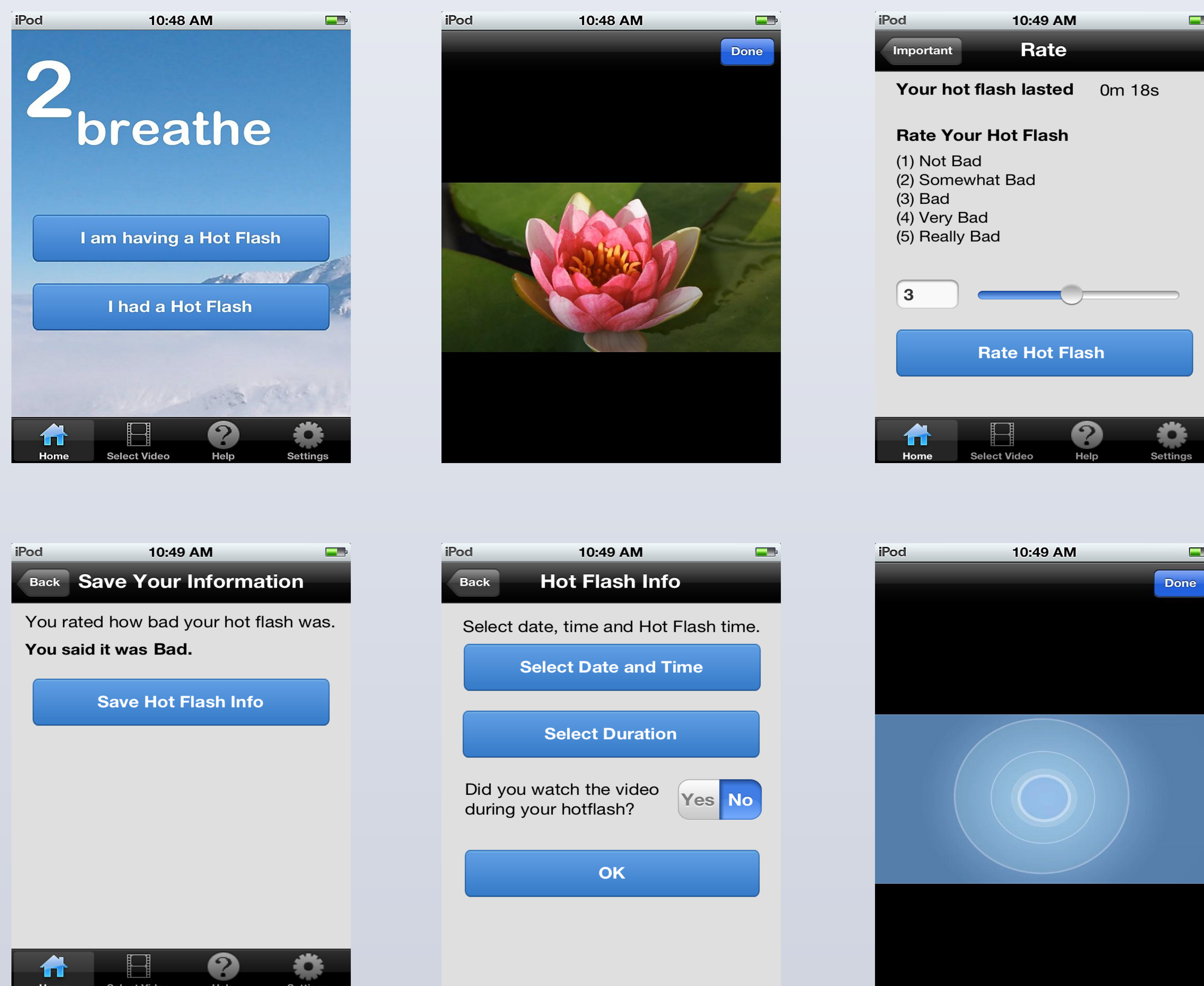
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Screenshots of the 2breathe program

Study Design

N = 19 prostate cancer patients have been enrolled in the study so far. Each participant receives an iPod for the duration of the 9-week long study. Participants are instructed in the slow breathing technique and to use the 2breathe application immediately at the first onset of a hot flash. Assessments take place at baseline and at 3, 6-, and 9-week follow up. 2breathe usage data has been extracted from each iPod

Results

Table 1: Demographics

Variable		N = 19	Mean (SD) or %
Age		19	67 (9.96)
Ethnicity	African American	16	84.21%
	Caucasian, Hispanic, other	3	15.79%
Education	High School	11	57.89%
	College	8	42.11%
Marital Status	Separated/Divorced/Single	9	47.37%
	Married	10	52.63%

Table 2: Acceptability

Variable	%
How easy was the program to use ?	Quite a bit - 42%; Extremely - 58%
How easy was the breathing exercise?	Moderately - 8%; Quite a bit - 17%; Extremely - 75%
How often did you use the program when experiencing a hot flash?	Rarely - 8%; Sometimes - 17%; Most of the time - 67%; Always - 8%.

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An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

Michael A. Diefenbach, Ph.D. Icahn School of Medicine at Mount Sinai; NYC
Kevin Durr, notsoldseparately.com; Philadelphia

Vasomotor Symptom (Hot Flashes) are a common side-effect of hormone therapy for prostate cancer survivors who experience a rising PSA. ²breathe is a non-pharmacological vasomotor symptom management app for men with hot flashes for Apple's OS, to facilitate a slow breathing exercise. Men are advised to use the app as soon as they feel a hot flash is starting and to use the program in guiding them to slow down their breathing to 6 breath per minute (5 sec inhale & 5 sec of exhale). Animations and music assist the patient to maintain the proper mechanism. Once the patient indicated that the hot flash is over, the program will prompt the patient to rate the severity of the hot flash. Date, time and duration are automatically assessed. If patients are unable to use the app at the time of the hot flash, patients are encouraged to use the breathing technique without the app, and enter in the pertinent information at a later point.

Preliminary data from a feasibility trial show that patients find the program and the intervention extremely easy to use and to implement. Preliminary efficacy data indicate a reduction of 35% in the occurrence of hot flashes from baseline to 9 weeks later.

